

SPL R4 Overview and Training – Over the Counter Drug Products Session July 30, 2008

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Structured Product Labeling

The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging medication information.

SPL's Goal is to make the labeling:

- **People friendly**
 - Labeling content in electronic format
 - Improve readability
 - Better access
- **Computer friendly**
 - Medication information that is **computer readable**
 - Structured labeling content and elements - Computer can “find” a specific section of the labeling and specific elements within labeling
- **Information system friendly**
 - Medication information in computer readable form - Easily imported into information systems
- **Publicly available**
 - Content of Labeling (up-to-date version) is made available by the FDA thru NLM (DailyMed) to consumers and health information suppliers

XML & XSL Stylesheet

- SPL is created using **EX**tensible **M**arkup **L**anguage (XML) – similar to HTML for webpages
- XML
 - Relatively human-legible
 - Machine readable
 - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML editing tools, SPL authoring tools, SPL conversion services, Xforms, etc...
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

SPL Stylesheet View/Source Code

CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

SPL Authoring Options

- SPL authoring tools helps you “write” SPL documents using the XML language.
- SPL conversion vendors – provide a conversion service
- SPL Authoring/Document Management Tools – to integrate into your IT environment
- XForms - Tool to create SPL content of labeling documents and the three future eList & eReg SPL documents. (similar to Word processing software) (used as a training tool)

Terminology

- Standard terminology is used for SPL listing data elements.
- Terminology Resources
 - National Cancer Institute Thesaurus
 - FDA DSC SPL web page (acceptable terms for use in SPL)
 - CDER (FDA) Data Standards Manual (for definitions)

Terminology

- Only controlled terminology is permitted in SPL documents
- Terminology lists are on FDA Data Standards Council's SPL web page:
<http://www.fda.gov/oc/datacouncil/spl.html>

Example of OTC SPL Terminology

OTC SPL Section Headings

LOINC Code	LOINC Name
34089-3	DESCRIPTION SECTION
34068-7	DOSAGE & ADMINISTRATION SECTION
51727-6	INACTIVE INGREDIENT SECTION
34067-9	INDICATIONS & USAGE SECTION
50569-3	OTC - ASK DOCTOR SECTION
50568-5	OTC - ASK DOCTOR/PHARMACIST SECTION
50570-1	OTC - DO NOT USE SECTION
50565-1	OTC - KEEP OUT OF REACH OF CHILDREN SECTION
53414-9	OTC - PREGNANCY OR BREAST FEEDING SECTION
53413-1	OTC - QUESTIONS SECTION
50566-9	OTC - STOP USE SECTION
50567-7	OTC - WHEN USING SECTION
51945-4	PACKAGE LABEL.PRINCIPAL DISPLAY PANEL
34071-1	WARNINGS SECTION

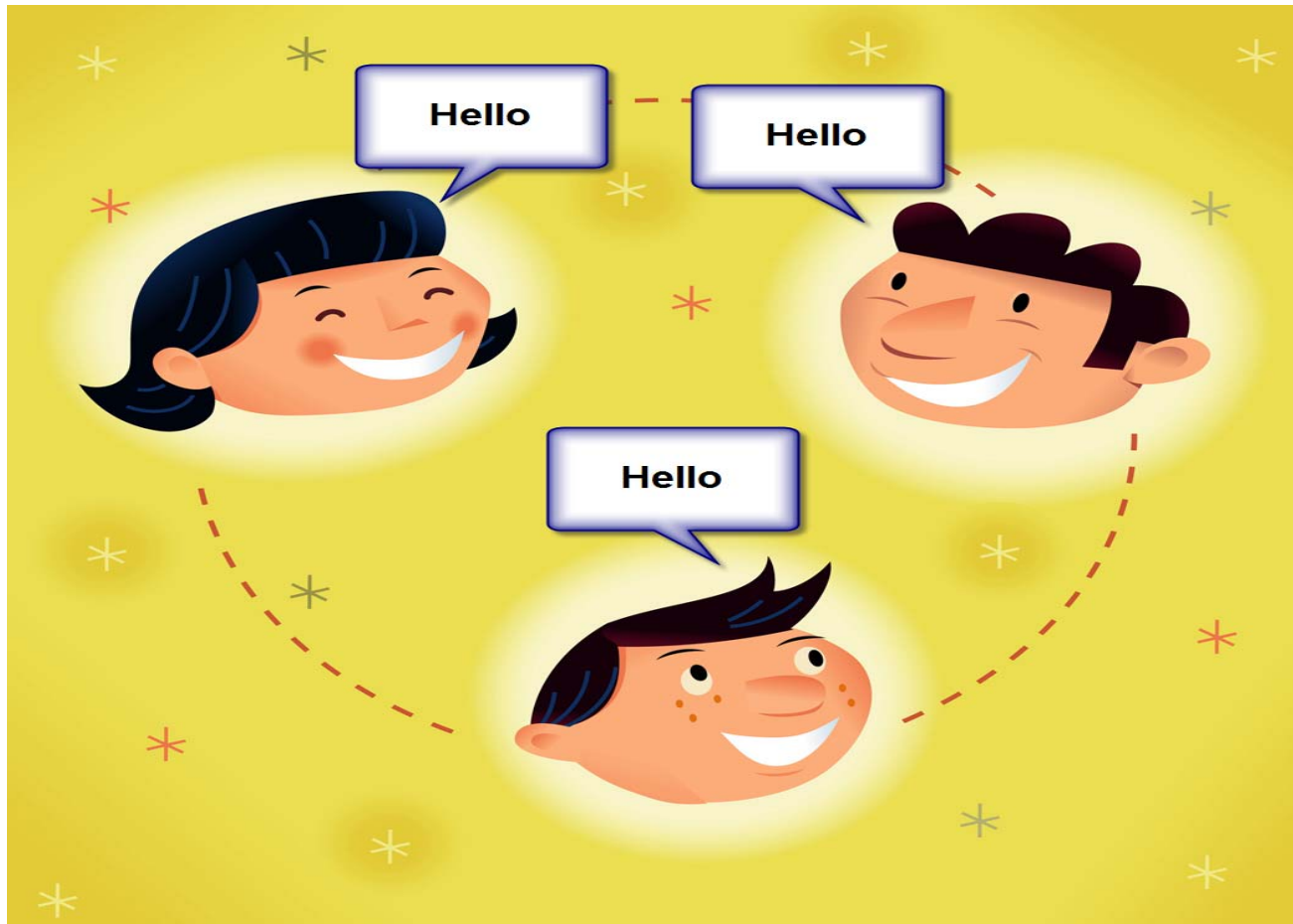
Communication

Verbal – Different Language



Communication

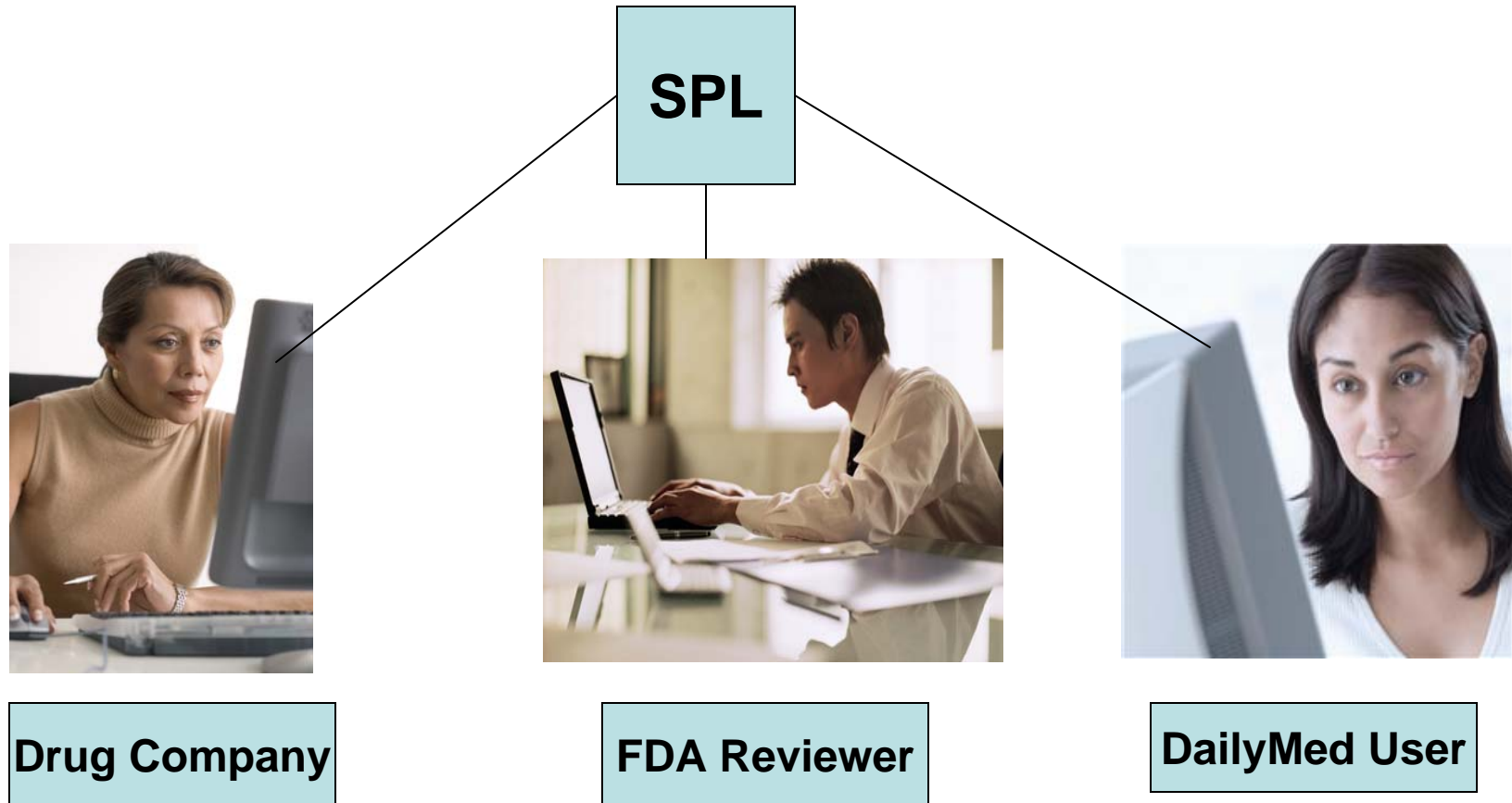
Verbal – Identical Language



SPL - Language

- SPL is a “language” that computers systems using the SPL standard can “understand”
- SPL document is a message that is used to exchange medication information (SPL content)
- Drug company
 - Creates SPL using SPL standard
 - Submits SPL to FDA
- FDA
 - Processes and validates SPL document using SPL standard
 - Transmits SPL to public repository (DailyMed/FACTS@FDA)
- DailyMed/FACTS@FDA/Health Information Supplier
 - Imports SPL into their system that uses the SPL standard
 - Displays and uses SPL data (label, listing data elements, etc..)

Information Exchange SPL



SPL is a standard that is used by drug companies, FDA and public to exchange or review or view medication information. All three entities use computer systems that “understand” SPL

Transition from Paper to Electronic Registration & Listing

- Changes in FD&C Act require electronic registration and listing for human prescription drugs, OTC, animal drug, biologic products
- FDA is adopting the use of extensible markup language (XML) files in SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

Benefits of Electronic Registration and Listing

- Electronic registration and listing process is more efficient and effective for industry and the Agency
- Accurate, up-to-date inventory of marketed drugs
- Eliminates data entry errors
- Well formed and properly created SPL files can be processed in minutes
- Use existing technology and data standard – **SPL (Used by FDA since 2005)**

More Benefits of Electronic Registration and Listing

- Data maintenance
 - Content of Labeling and listing information in one file.
 - Registrant can list all it's establishments in one file.
 - Updates? Update one file instead of creating many paper forms and resubmit.
- Eliminates the use of paper forms for listing and registration

Replace Paper Forms (2656, 2657, 2658)

Save As...	Print	Next Page	Print Page	Form Approved: OMB No. 0910-0045, Expiration Date: December 31, 2007	See OMB Statement on Payments
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT <small>(a) Instructions and Public Law 92-287</small>				FDA USE ONLY	FDA USE ONLY
NOTICE: The report is required by law (21 C.F.R. 272.22). Failure to report can result in imprisonment for not more than 5 years or a fine of not more than \$1,000, or both. (FDCA, Art. Section 302)				LABELER CODE	REGISTRATION NUMBER
SECTION A - SITE INFORMATION					
REPORTING FIRM NAME				STATE OF INC.	
SITE ADDRESS (No P.O. Box)				SITE TELEPHONE NUMBER ()	
CITY	STATE	ZIP CODE	COUNTRY	BUSINESS CATEGORY: <input type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY	
SITE MAILING ADDRESS (If different from above)					
CITY	STATE	ZIP CODE	COUNTRY	SITE INTERNET/EMAIL ADDRESS	
DOING BUSINESS AS (DBA) NAME OF FIRM (If appropriate)					
PARENT COMPANY NAME					
REASON(S) FOR SUBMISSION <input type="checkbox"/> Firm Registration <input type="checkbox"/> Expansion of Address Site <input type="checkbox"/> Change in Ownership <input type="checkbox"/> LC Assignment <input type="checkbox"/> Name Change		TYPE OF OWNERSHIP <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> S- or C-Corporation <input type="checkbox"/> Other		PERSON SUBMITTING DATA AND TELEPHONE BUSINESS TYPE <input type="checkbox"/> Distributor <input type="checkbox"/> Foreign Country <input type="checkbox"/> Analytical Lab <input type="checkbox"/> Other	
SECTION B - FIRM COMPLIANCE MAILING ADDRESS (For Annual Listing Report and/or Firm Correspondence)					
NUMBER AND STREET ADDRESS P.O. BOX AND ATTENTION LINE and/or Internal Mail Code				TELEPHONE NUMBER ()	
CITY	STATE	ZIP CODE	COUNTRY	COMPLIANCE INTERNET/EMAIL ADDRESS	
SECTION C - ADDITIONAL FIRM AND SITE INFORMATION					
NAME OF OWNER, PARTNER OR OFFICER		TITLE		POSITION	
OTHER FIRMS DOING BUSINESS AT THIS SITE					
LABELER CODE	FIRM NAME	LABELER CODE	FIRM NAME		
SECTION D - SIGNATURE					
SIGNATURE OF AUTHORIZING OFFICIAL			TITLE		DATE
DISCLAIMER/CERTIFICATION: As a Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification Form FDA 3569 to the registered manufacturer(s). My signature and phone number are listed below.					
RETURN THIS FORM TO:			SIGNATURE OF DISTRIBUTOR		
CDCE AND CDRA ADMINISTRATION CDCE/CDRA REGISTRATION AND LISTING (HFD-323) 5601 FISKE LANE ROCKVILLE, MD 20857 ROCKVILLE, MICHIGAN HAS GOV			DISTRIBUTOR'S TELEPHONE NUMBER		
FORM FDA 3569 (07/07) (P0707)			NOTE: Validation of this form is not to be construed as FDA approval of the establishment or its products. PREVIOUS EDITION IS OBSOLETE.		

[illegible][illegible]

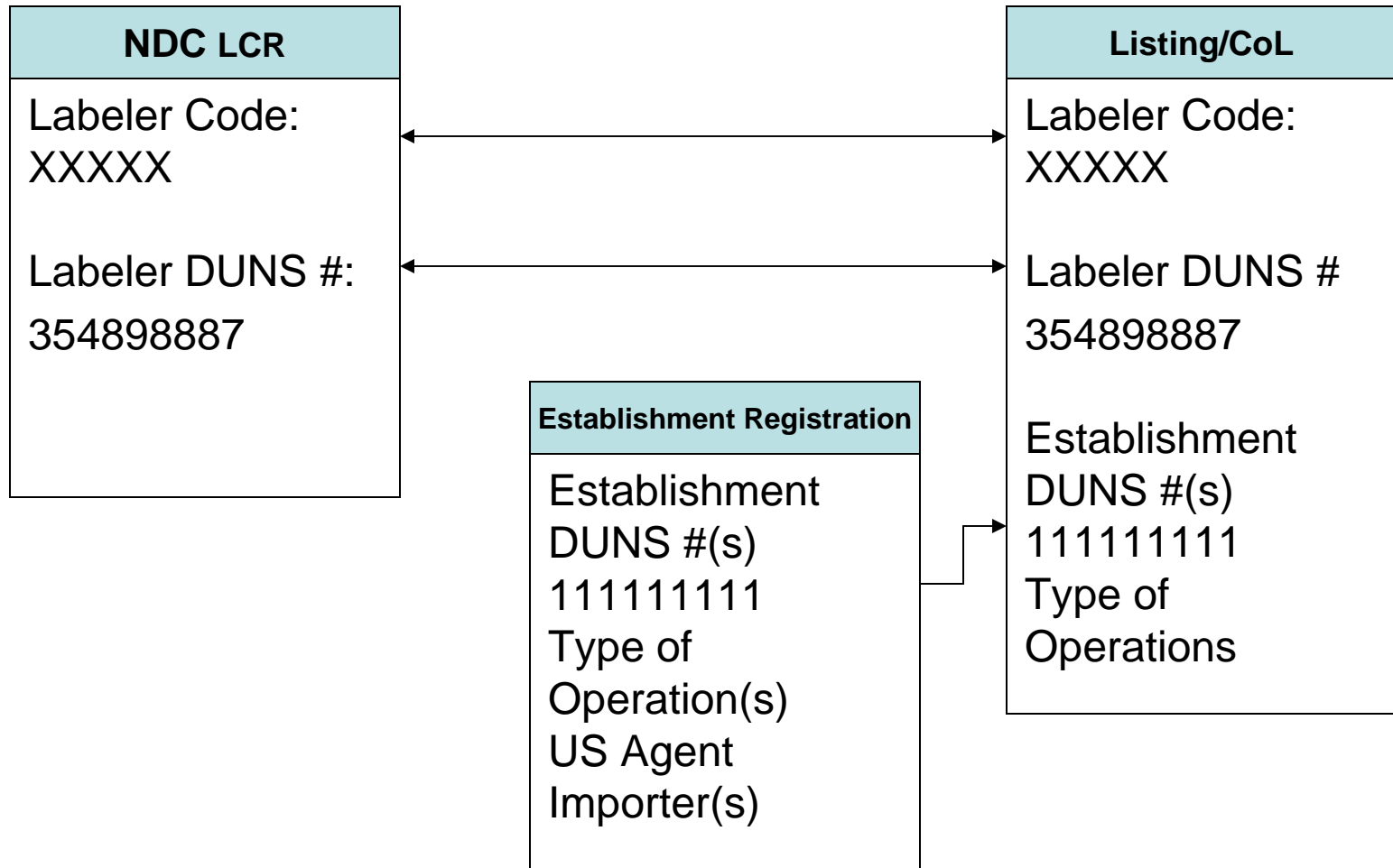
Three e-Files for Registration & Listing - SPL Format

- NDC Labeler Code Request
- Establishment Registration
- Content of labeling (CoL)/Listing
- Benefits
 - Electronically register establishments and list for **OTC** drug products
 - Posting of **OTC** labels w/rest of FDA electronic labels

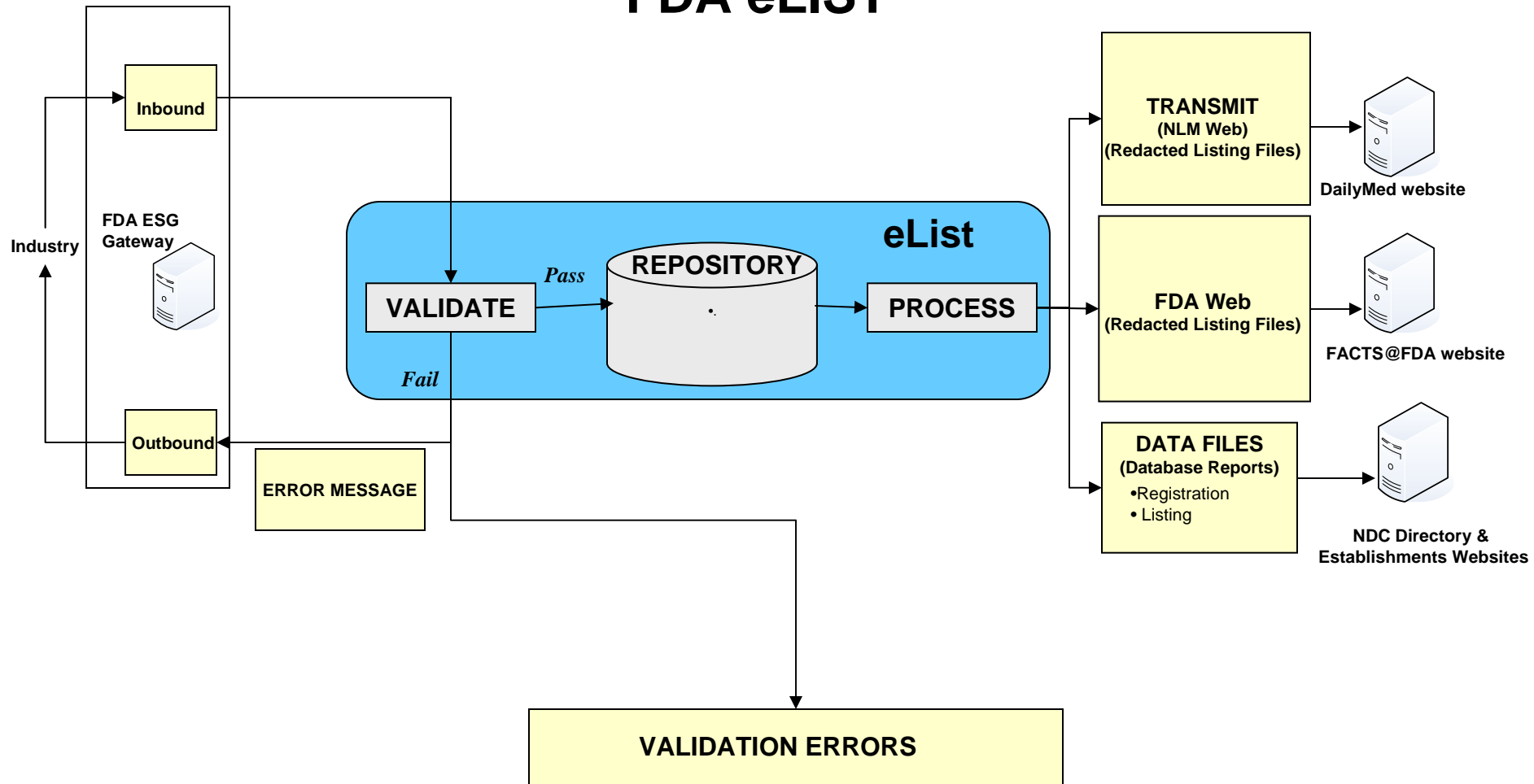
Order of Submissions for SPL R4

1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
 2. CoL/Listing SPL
- CoL/Listing validates against data submitted in NDC LCR and ER SPL

Data Source – SPL Documents



FDA eLIST



OTC Listing SPL Mock-Up

Drug Facts Text
Text, text, text, text

**Drug Facts
(content of labeling text)**

Principal Display Text

**Principal display panel
text**



**Carton and/or container
labeling**

A screenshot of a web-based form for drug listing. The form has multiple sections with labels and input fields. The sections include: 'Product Information' (Product Name, NDC, etc.), 'Marketing Information' (Marketing Name, Strength, etc.), 'Establishment Information' (Establishment Name, Address, etc.), 'Product Characteristics' (Description, etc.), and 'Packaging' (Packaging Description, etc.). At the bottom, there is a small image of a red and white capsule.

**Drug listing data elements
Establishment information
Marketing information**

Image of product (optional)

OTC Content of Labeling

- Sec. 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.
 - (c) *Content requirements.* The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.
 - (d) *Format requirements.* The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section shall be presented on OTC drug products in accordance with the following specifications. In the interest of uniformity of presentation, FDA strongly recommends that the Drug Facts labeling be presented using the graphic specifications set forth in appendix A to part 201.

SPL R4 Documentation

(Recommended Reading)

- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Draft)
- Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v1.0
- Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v1.0
- Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms v1.0
- SPL Docket 92S-0251 - Drug Establishment Registration and Drug Listing

Collaboration with Industry

- HL7 SPL Implementation Working Group
 - OTC Subteam
- Drug companies (workshops, individual assistance)
- Vendors (workshops, individual assistance)

Accomplishments

- FDA (CDER) has been using SPL standard for almost 3 years
- Quality of SPL documents has improved significantly since October 2005
- Over **3,950** SPL documents posted on DailyMed (as of July 2008)

Participation in Voluntary Pilot Program

- Start with NDC Labeler Code Request
 - Receive feedback from Agency
 - Slowly acclimate to the new electronic eList system
 - Prepare for June 1, 2009

Future SPL R4 Training/Meetings

- SPL R4 Training Session F2F – July 31, 2008
- SPL R4 Training – DIA Web Conference – September 9, 2008
- SPL R4 Meeting – DIA F2F – October 2008
- SPL R4 Meeting – GPhA – October 2008

Stay Informed

- FDA Data Standards Council website listserv
 - <http://www.fda.gov/oc/datacouncil/>
- Health Level Seven Working Group – OTC Subteam

Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)